

JAN - 7 2005

K043020

**GALAXY™ 3.2 Spinal System  
Summary of Safety and Effectiveness  
October 2004**

**I. Company:** Medtronic Sofamor Danek, Inc. USA  
1800 Pyramid Place  
Memphis, TN 38132  
(901) 396-3133

**II. Proposed Proprietary Trade Name:** GALAXY™ 3.2 Spinal System

**III. Spinal Interlaminar Fixation Orthosis**

**IV. Product Description**

The GALAXY™ 3.2 Spinal System consists of a variety of shapes and sizes of screws, hooks, rods and connecting components, which can be rigidly locked to the rod in a variety of configurations, with each construct being tailor-made for the individual case. This system is intended for posterior use only.

Titanium implant components from other previously cleared Medtronic Sofamor Danek Spinal Systems can be used in conjunction with the GALAXY™ 3.2 Spinal System. These systems include the TSRH®, CD HORIZON®, DYNALOK™ PLUS, DYNALOK CLASSIC™ spinal systems and VERTEX™ Reconstruction Systems. Additionally, titanium ATLAS cable may be used with this system at the surgeon's discretion.

The GALAXY™ 3.2 Spinal System is fabricated from medical grade titanium or titanium alloy.

The GALAXY™ 3.2 Spinal System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, cervical and/or sacral spine. The GALAXY™ 3.2 Spinal System implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. If necessary, the GALAXY™ 3.2 Spinal System can be connected to the VERTEX™ Reconstruction System through a rod connector.

**V. Indications**

When intended to promote fusion of the cervical spine and the thoracic spine, (C1-T3), the GALAXY™ 3.2 Spinal System is indicated for the following:  
DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors.

***Hooks and Rods***

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

***Screws/Connectors***

The use of screws is limited to placement in T1-T3 only. Screws are not labeled to be placed in the posterior cervical spine.

Titanium ATLAS™ Cable used with the GALAXY™ 3.2 Spinal System allows for cable attachment to the posterior cervical or thoracic spine.

**VI. Substantial Equivalence**

Documentation was provided which demonstrated the GALAXY™ 3.2 Spinal System to be substantially equivalent to VERTEX™ Reconstruction System components previously cleared in K042402.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Richard Treharne, Ph.D.  
Senior Vice President Regulatory Affairs  
Medtronic Sofamor Danek, Inc.  
1800 Pyramid Place  
Memphis, Tennessee 38132

Re: K043020

Trade/Device Name: Galaxy™ 3.2 Spinal System  
Regulation Number: 21 CFR 888.3050  
Regulation Name: Spinal interlaminar fixation orthosis  
Regulatory Class: II  
Product Code: KWP  
Dated: November 1, 2004  
Received: November 3, 2004

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

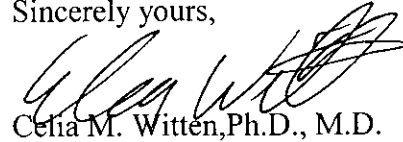
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Richard W. Treharne, Ph.D.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', is written over the typed name.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K043020

Device Name: GALAXY™ 3.2 Spinal System

Indications for Use

When intended to promote fusion of the cervical spine and the thoracic spine, (C1-T3), the GALAXY™ 3.2 Spinal System is indicated for the following:

DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors.

***Hooks and Rods***

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

***Screws/Connectors***

The use of screws is limited to placement in T1-T3 in treating thoracic conditions only.

Screws are not intended to be placed in the cervical spine.

Titanium ATLAS™ Cable used with the GALAXY™ 3.2 Spinal System allows for cable attachment to the posterior cervical or thoracic spine.

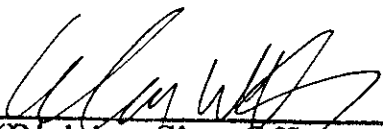
Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number K043020 0000004